DEC 0 5 2001

K013676

Special 510(k) Summary - Device Modification
Summary of Safety and Effectiveness for the
TRIDENT® HEMISPHERICAL SHELLS (AD and AD-HA)

Proprietary Name:	Trident® Hemispherical Acetabular Shells
Common Name:	Artificial Hip Replacement Components - Acetabular
Classification Name and Reference:	Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Non-Porous Uncemented Prosthesis 21 CFR §888.3353
Proposed Regulatory Class:	Class II
Device Product Code:	87 MEH
For Information contact:	Jennifer A. Daudelin, Regulatory Affairs Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ ~~07070-2584~~ 07401-1677 (201) 934-4354 Fax: (201) 760-8435

This Special 510(k) submission is intended to address a surface coating modification from plasma sprayed CP Titanium to arc deposited CP Titanium to the Trident® Hemispherical Shells with Plasma Spray and/or Hydroxylapatite (HA) Coating. The intended use, manufacturing methods, materials, packaging and sterilization of the subject device are identical to those of predicate devices. The predicate Trident® Hemispherical Shells with Plasma Spray and HA were found substantially equivalent via the 510(k) process in K001448 and K001449 respectively. Likewise, the Arc Deposited (AD) CP Titanium surface roughness coating was found substantially equivalent in 510(k) #K943054, and the AD-HA combination was found substantially equivalent via 510(k) #K942900.

The substrate of the predicate hemispherical shells is Titanium (Ti-6Al-4V ELI) Alloy conforming to ASTM F-620. The surface coating of Arc Deposited CP Titanium meets ASTM standard F-67 while the Hydroxylapatite coating conforms to ASTM F-1185. The subject devices have a shell size or outer diameter range from 42mm to 82mm. Like the predicate devices, the subject devices are single-use devices intended for cementless fixation within the prepared acetabulum in primary or revision total hip arthroplasty. The subject acetabular shells are intended for use with mating Trident Polyethylene Cup Inserts and all legally marketed Howmedica Osteonics femoral head and femoral stem components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Jennifer A. Daudelin
Regulatory Affairs
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

DEC 0 5 2001

Re: K013676
Trade/Device Name: Trident Hemispherical Shells (AD and AD-HA)
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: MEH
Dated: November 6, 2001
Received: November 7, 2001

Dear Ms. Daudelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K013676

Device Name: Trident® Hemispherical Shells (AD and AD-HA)

Indications for Use:

The subject Trident Acetabular Shells are single-use devices intended for cementless fixation within the prepared acetabulum. The subject acetabular shells are intended for use with mating Trident Polyethylene Cup Inserts.

Indications:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark A. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013676